Substitute for form 1449A-B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

 C	omplete if Known
Application Number	10/549,506 (371 of PCT/DK04/00193)
International Application Filing Date	March 22, 2004
371(c) Date	July 7, 2006
First Named Inventor	ANDERSEN, Kim Vilbour
Group Art Unit	
Examiner Name	
Attorney Docket Number	0272us310

			U.	S. PATENT DOCUMENTS		
Examiner Initials	Cite No.	U.S. Patent Do Number	Cument Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM/DD/YYYY	Pages, Columns, lines, Where Relevant Passages or Relevant Figures Appeal
	1	4,784,950		Hagen et al.	11/15/1998	
	2	4,904,584		Shaw	02/27/1990	
	3	5,041,376		Gething et al.	08/20/1991	
***************************************	4	5,180,583		Hedner	01/19/1993	
	5	5,225,537		Foster	07/06/1993	
	6	5,288,629		Berkner	02/22/1994	
	7	5,460,950		Barr et al.	10/24/1995	
	8	5,580,560		Nicolaisen et al.	12/03/1996	
	9	5,648,254		Mulvihill et al.	07/15/1997	
	10	5,824,634		Merchant	10/20/1998	
	11	5,861,374		Berkner et al.	01/19/1999	
	12	5,891,843		Turecek et al.	04/06/1999	
	13	5,965,425		Barr et al.	10/12/1999	
	14	5,986,079		Barr et al.	11/16/1999	
	15	6,013,620		Turecek et al.	01/11/2000	
	16	6,017,882		Nelsestuen	01/25/2000	

				FORFIGE	N PATENT DOCUMEN	TS		
Examiner Initials	Cite No.	Office	Foreign Patent Docum Number		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM/DD/YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т
	17	EP	0 370 205	A2	Kyowa Hakko Kogyo Co., Ltd.	05/30/1990		
	18	EP	0 512 011	B1	Immuno Aktiengesellschaft	11/11/1992		
	19	wo	88/10295	A1	Novo Industri A/S	12/29/1988		

Examiner /Samuel Liu/	Date Considered	07/13/2009

JUL 2 0 2008 up titute for form 1449A-B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

C	omplete if Known
Application Number	10/549,506 (371 of PCT/DK04/00193)
International Application Filing Date	March 22, 2004
371(c) Date	July 7, 2006
First Named Inventor Group Art Unit	ANDERSEN, Kim Vilbour
Examiner Name	
Attorney Docket Number	0272us310

 20	wo	91/11514	A1	Zymogenetics, Inc.	08/08/1991	T
21	wo	92/15686	A1	Zymogenetics, Inc.	09/17/1992	T
22 -	wo	94/27631	A1	Zymogenetics, Inc.	12/08/1994	T
23	wo	96/00577	A1	COR Therapeutics, Inc.	01/11/1996	
24	wo	98/32466	A1	Polymasc Pharmaceuticals Pic	07/30/1998	
 25	wo	98/35026	A1	Novo Nordisk A/S	08/13/1998	T
26	wo	99/03498	A1	Novo Nordisk A/S	01/28/1999	T
27	wo	99/03887	A1	Bolder Biotechnology, Inc.	01/28/1999	T
28	wo	99/20767	A1	Regents of the University of Minnesota	04/29/1999	
29	wo	99/66031	A2	Baxter Aktiengesellschaft	12/23/1999	
30	wo	00/26230	A1	Novo Nordisk A/S	05/11/2000	T
31	wo	00/26354	A1	Novo Nordisk A/S	05/11/2000	Т
32	wo	00/28065	A1	Novo Nordisk A/S	05/18/2000	Т
33	wo	00/54787	A1	The Children's Hospital of Philadelphia	09/21/2000	
34	wo	00/66753	A2	Regents of the University of Minnesota	11/09/2000	
35	wo	01/58935	A2	Maxygen ApS	08/16/2001	T
 36	wo	01/83725	A1	Novo Nordisk A/S	11/08/2001	T
37	wo	02/077218	A1	Novo Nordisk A/S	10/03/2002	
38	wo	02/22776	A2	Novo Nordisk A/S	03/21/2002	T

Examiner	/C11:-/	Date	07(40)0000	
Signature	/Saniuei Liu/	Considered	07/13/2009	

Substitution of form 1449a-BiPTO

C	omplete if Known
Application Number	10/549,506 (371 of PCT/DK04/00193)
International Application Filing Date	March 22, 2004
371(c) Date	July 7, 2006
First Named Inventor	ANDERSEN, Kim Vilbour
Group Art Unit	
Examiner Name	
Attorney Docket Number	0272us310

(use as many sheets as necessary)

	39	wo	02/38162	A1	Scripps Reseach Institute	05/16/2002	
	40	wo	03/027147	A2	Novo Nordisk A/S	04/03/2003	
	41	wo	03/037932	A2	Nova Nordisk A/S	05/08/2003	
••••	42	wo	03/055512	A1	Novo Nordisk A/S	07/10/2003	
	43	wo	03/093465	A1	Maxygen ApS	11/13/2003	
•	44	wo	2004/029091	A2	Maxygen ApS	04/08/2004	
***************************************	45	wo	2004/083361	A2	Maxygen Holdings Ltd.	09/30/2004	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal sarial, symposium, catatog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	т
	46	Bharadwaj, D., et al., "Factor VII Central—A Novel Mutation in the Catalytic Domain that Reduces Tissue Factor Binding, Impairs Activation by Factor XA, and Abolishes Amidolytic and Coagulant Activity," J. Biological Chemistry 271(48):30685-30691 (1996)	
	47	Bjoern, S., et al., "Human Plasma and Recombinant Factor VII – Characterization of O-Glycosylations at Serine Residues 52 and 60 and Effects of Site-Directed Muttagenesis of Serine 52 to Alanine," J. Biological Chemistry 266(17):11051-11057 (1991)	
	48	Chang, J-Y., et al., "Replacing the First Epidermal Growth Factor-like Domain of Factor IX with That of Factor VII Enhances Activity In Vitro and in Canine Hemophilia B," J. Clin. Invest. 100(4):886-892 (1997)	
	49	Chang, Y-J., et al., "Engineered Recombinant Factor VII Q ²¹⁷ Variants with Altered Inhibitor Specificities," <i>Biochemistry</i> 38:10940-10948 (1999)	
	50	Cheung, W.F. et al., "Localization of an Epitope of Calcium-Dependent Monoclonal Antibody to the N-Terminal Region of the Gla Domain of Human Factor VII", Thrombosis Research, 79(2):199-206 (1995).	

Examiner	(Comput Lint	I Date	0711010000
Signatura	/Samuer Liu/	Considered	07/13/2009
Signature		Louisidered	



INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

51	Cheung, W.F. et al., "Localization of a metal-dependent epitope to the amino terminal residues 33-40 of human factor IX", <i>Thrombosis Research</i> , 80(5):419-427 (1995).	
5,2	Database EMBL, "Gallus gallus anticoagulant protein C precursor (PROC) mRNA, complete cds", Database Accession No. AF465270, Feb. 2 2003.	
53	Database UNIPROT, "Coagulation factor VII (EC 3.4.21.21) (Serum prothrombin conversion accelerator)", Database Accession No. P22457, Aug. 1 1991.	
54	Dickinson, C.D., et al., "Identification of surface residues mediating tissue factor binding and catalytic function of the serine protease factor VIIa," <i>Proc. Natl. Acad. Sci. USA</i> 93:14379-14384 (1996).	
55	Dickinson, C.D., et al., "Active Site Modification of Factor VIIa Affects Interactions of the Protease Domain with Tissue Factor," J. Biological Chemistry 272(32):19875-19879 (1997).	
56	Dickinson, C. D. et al., "Influence of Cofactor Binding and Active Site Occupancy on the Conformation of the Macromolecular Substrate Exosite Of Factor VIIa", J. Mol. Biol. 277:959-971 (1998).	×
57	Hedner, U. "NovoSeven as a universal haemostatic agent." Blood Coagul. Fibrinolysis 11 Suppl 1:S107-S111 (2000).	
58	Higashi, S. et al. "Molecular mechanism of tissue factor-mediated acceleration of factor VIIa activity," J. Biol. Chem. 271(43):26569-74 (1996).	
59	Huang, Q., et al., "Substrate Recognition by Tissue Factor-Factor VIIa – Evidence for Interaction of Residues Lys ¹⁶⁶ and Lys ¹⁶⁶ of Tissue Factor with the 4-Carbox yglutamate-Rich Domain of Factor X," <i>J. Biological Chemistry</i> 271(36):21752-21757 (1996).	
60	fino, M., et al., "Functional Consequences of Mutations in Ser-52 and Ser-60 in Human Blood Coagulation Factor VII," Archives Biochem. Biophys. 352(2):182-192 (1998).	
61	Iakhiaev, A. et al. "The role of catalytic cleft and exosite residues of factor VIIa for complex formation with tissue factor pathway inhibitor", <i>Thromb. Haemost.</i> 85(3):458-463 (2001).	

1	Examiner	(Compathial	Date	07//0/0000	
1	Signature	/Samuel Liu/	Considered	07/13/2009	

JUL 2 0 2006 W

Complete if Known fitute for form 1449A-B/PTO Application Number 10/549,506 (371 of PCT/DK04/00193) International Application March 22, 2004 INFORMATION DISCLOSURE Filing Date STATEMENT BY APPLICANT 371(c) Date July 7, 2006 First Named Inventor ANDERSEN, Kim Vilbour Group Art Unit Examiner Name (use as many sheets as necessary) Attorney Docket Number 0272us310

62	Jin, J., et al., "Factor VIIa's First Epidermal Growth Factor-like Domain's Role in Catalytic Activity," Biochemistry 38:1185-1192 (1999).
63.	Jin, J. et al., "Four Loops of the Catalytic Domain of Factor VIIa Mediate the Effect of the First EGF-like Domain Substitution on Factor VIIa Catalytic Activity", J. Mol. Biol. 307:1503-1517 (2001).
64 ·	Kelly, C.R., et al., "Ca ²⁺ Binding to the First Epidermal Growth Factor Module of Coagulation Factor VIIa Is Important for Cofactor Interaction and Proteolytic Function," J. Biological Chemistry 272(28):17467-17472 (1997)
65	Kemball-Cook, G., et al., "Coagulation Factor VII Gln ¹⁰⁰ Arg—Amino Acid Substitution at the Epidermal Growth Factor 2-Protease Domain Interface Results in Severely Reduced Tissue Factor Binding and Procoagulant Function," <i>J. Biological Chemistry</i> 273(14):8516-8521 (1998).
66	Leonard, B.J.N., et al., "Activation and Active Site Occupation Alter Conformation in the Region of the First Epidermal Growth Factor-like Domain of Human Factor VII," J. Biological Chemistry 275(45):34894-34900 (2000).
67	Mayer, S.A. "Ultra-early hemostatic therapy for intracerebral hemorrhage," Stroke 34(1):224-229 (2003).
68	Nelsestuen, G.L. et al. "Elevated function of blood clotting factor VIIa mutants that have enhanced affinity for membranes. Behavior in a diffusion-limited reaction," J. Biol. Chem. 276(43):39825-39831 (2001).
.69	Neuenschwander, P.F. et al., "Alteration of the Substrate and Inhibitor Specificities of Blood Coagulation Factor VIIa: Importance of Amino Acid Residue K192", Biochemistry 34:8701-8707 (1995).
70	Persson, E., et al., "Site-directed mutagenesis but not γ-carboxylation of Glu-35 in factor VIIa affects the association with tissue factor," FEBS Letters 385:241-243 (1996).
71	Persson, E., "Characterization of the interaction between the light chain of factor VIIa and tissue factor," FEBS Letters 413:359-363 (1997).

Evaminer		Date	
- Adminion	10	; Duit	1 07/40/0000
Cinnatura	(29miei Fin)	Considered	1 07/13/2009
Signature		Considered	

JUL 20 1900 MILE for form 1449A-BIPTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

C	omplete if Known
Application Number	10/549,506 (371 of PCT/DK04/00193)
International Application Filing Date	March 22, 2004
371(c) Date	July 7, 2006
First Named Inventor	ANDERSEN, Kim Vilbour
Group Art Unit	
Examiner Name	
Attorney Docket Number	0272us310

72	Persson, E., et al., "Ca ²⁺ Binding to the First Epidermal Growth Factor-like Domain of Factor VIIa Increases Amidolytic Activity and Tissue Factor Affinity," J. Biological Chemistry 272(32):19919-19924 (1997).	
73	Petersen, L.C., et al., "Binding of Zn ²⁺ to a Ca ²⁺ loop allosterically attenuates the activity of factor VIIa and reduces its affinity for tissue factor," <i>Protein Science</i> 9:859-866 (2000).	
74	Petrovan, R.J., et al., "Role of Residue Phe ²²⁵ in the Cofactor-Mediated, Allosteric Regulation of the Serine Protease Coagulation Factor VIIa," <i>Biochemistry</i> 39:14457-14463 (2000).	
75	Petrovan, R.J., et al., "Residue Met(156) contributes to the labile enzyme conformation of coagulation factor VIIa" J. Biol. Chem. 276(9):6616-6620 (2001).	
76	Ruf, W., et al., "Importance of Factor VIIa Gla-Domain Residue Arg-36 for Recognition of the Macromolecular Substrate Factor X Gla-Domain," <i>Biochemistry</i> 38:1957-1966 (1999)	
77	Shah, A.M., et al., "Manipulation of the membrane binding site of vitamin K-dependent proteins: Enhanced biological function of human factor VII," Proc. Natl. Acad. Sci. USA 95:4229-4234 (1998).	
78	Shobe, J., et al., "Macromolecular Substrate Affinity for the Tissue Factor-Factor VIIa Complex is Independent of Scissile Bond Docking," J. Biological Chemistry 274(34):24171-24175 (1999).	
79	Shobe, J., et al., "Regulation of the Catalytic Function of Coagulation Factor VIIa by a Conformational Linkage of Surface Residue Glu 154 to the Active Site," Biochemistry 38:2745-2751 (1999).	
80	Sorensen, B.B. et al. "Incorporation of an active site inhibitor in factor VIIa alters the affinity for tissue factor," J. Biol. Chem. 272(18):11863-11868 (1997).	
81	Sridhara S. et al. "Activation of a recombinant human factor VII structural analogue alters its affinity of binding to tissue factor," Am. J. Hematol. 53(2):66-71 (1996).	
82	Zhang, E. et al., "Structure of Extracellular Tissue Factor Complexed with Factor VIIa Inhibited with a BPTI Mutant," J. Mol. Biol. 285(5):2089-2104 (1999).	

		·	
Evaminar	Committee	Date	
LAGIIII E	/Oditivet Liu/	Daic	07/49/0000
Cionatura		Considered	1 07/13/2009 1
orgradule (Considered	